

# In the United States Court of Federal Claims

No. 03-2876V

(Filed Under Seal: February 4, 2015)  
(Reissued for Publication: February 20, 2015)<sup>1</sup>

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EILISE MORIARTY, a minor, by her  
parents and natural guardians, MARIE  
LOUISE MORIARTY and STEPHEN  
MORIARTY,

Petitioners,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

\*\*\*\*\* \*

\* National Childhood Vaccine Injury  
\* Act; Motion for Review of Special  
\* Master's Decision Denying Relief;  
\* MMR Vaccination; Application of  
\* Althen Test; Assessment of Expert  
\* Testimony.

*Clifford J. Shoemaker*, Shoemaker, Gentry & Knickelbein, Vienna, Virginia, for  
Petitioners.

*Alexis B. Babcock*, with whom were *Joyce R. Branda*, Acting Assistant Attorney General,  
*Rupa Bhattacharyya*, Director, *Vincent J. Matanoski*, Deputy Director, and *Catharine E.*  
*Reeves*, Assistant Director, Torts Branch, Civil Division, U.S. Department of Justice,  
Washington, D.C., for Respondent.

## OPINION AND ORDER

WHEELER, Judge.

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<sup>1</sup> This opinion originally was issued under seal on February 4, 2015. Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims ("Vaccine Rules"), the parties had 14 days within which to propose redactions to the opinion prior to publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

Currently before the Court is Petitioners' Motion for Review of the Special Master's August 15, 2014 decision denying compensation for an injury allegedly caused by a vaccine. The matter is fully briefed, and the Court heard oral argument on January 6, 2015. For the reasons explained below, the Court denies Petitioners' Motion for Review and affirms the decision of the Special Master.

On December 31, 2003, Petitioners filed a petition on behalf of their daughter Eilise for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 et seq. ("Vaccine Act"). The original petition was based on a claim that vaccines had caused Eilise to have autism. The case was stayed pending the outcome of the Omnibus Autism Proceeding ("OAP") established by the Office of Special Masters ("OSM") to address large numbers of autism claims. After OSM issued several decisions in OAP test cases, Petitioners filed an amended petition on July 14, 2011, removing autism claims and seeking on behalf of their daughter compensation for a seizure disorder, encephalopathy, and a decline in cognitive and motor functions caused by vaccination. The parties filed expert reports and additional evidence, and the Special Master then assigned to the case held an entitlement hearing. See Transcript of Proceedings, May 6, 2013 ("Tr."). In September 2013, the case was transferred to the Special Master whose decision denying compensation is the subject of this review. After both parties declined to request a new hearing in light of the reassignment, the Special Master issued his decision based on the record. See Moriarty v. Sec'y of Health & Human Servs., No. 03-2876V, 2014 WL 4387582 (Fed. Cl. Spec. Mstr. Aug. 15, 2014). Petitioners filed their Motion for Review on September 15, 2014.

## Background

### A. Facts

Eilise Moriarty was born in 1996, and had trouble walking and talking from a young age. At two years old she was referred to Children's National Medical Center for evaluation of developmental delay. At age three, she was diagnosed with hypotonia and developmental delay, including delayed language development. Moriarty, 2014 WL 4387582, at \*2. Eilise also had several surgeries to correct outward deviation of the eyes, and in March 2000, to remove her tonsils and adenoids. Id. at \*3. She continued to have significant delays in development of motor skills, and severe delays in articulation. Id. In fall 2000, she began a special education preschool program, and a progress report in October 2000 showed that she was making improvements in her fine motor and speech skills. Id.

Eilise's school in Virginia required her to have certain vaccinations before returning to school in January 2001. On January 2, 2001, she received her second measles, mumps and rubella ("MMR") vaccination together with diphtheria, tetanus, and pertussis and inactivated polio vaccinations. Petitioners' claim is based only on the MMR vaccine. Id. Petitioners alleged that on January 7, 2001, five days after the

vaccinations, Eilise suffered a seizure while she was at home with her older brother. Although Respondent disputed the characterization of this event as a seizure, the Special Master found that this event was in fact a seizure for the purposes of determining the timing of Eilise's possible reaction to the MMR vaccination. Id. at \*4. About two weeks later, Eilise suffered a grand mal seizure at school and was taken to the hospital, where she had another seizure and was transferred to Inova Fairfax hospital for treatment. At Inova Fairfax she continued to have seizures and the treating physician diagnosed her with "new onset seizures." Id. at \*5. On January 30, 2001, two days after she was discharged from Inova Fairfax, Eilise was seen at Johns Hopkins Medical Center, where the doctor assessing her record noted the seizures had unknown causes. Id. at \*6. In the next few months until June 2001, Eilise continued to have frequent seizures, and was treated several times at Inova Fairfax. When she was admitted on March 26, 2001, her mother reported that Eilise had experienced more than 20 episodes of seizures in the prior three days, and that she would fall to the floor during each one. Her mother also reported that at this same time Eilise's expressive language skills substantially declined. Id. at \*6-\*7.

In June 2001, Eilise began a ketogenic diet for treatment of her seizures under the supervision of Johns Hopkins Hospital. The diet was very successful: she was reportedly seizure-free after beginning the diet except for a few incidents involving improper ingredients in her food. In January 2002 in a follow-up visit to Johns Hopkins, the treating physician noted that Eilise was still on the ketogenic diet and free of seizures, and no longer taking any seizure medications. He recommended occupational, physical, and speech therapy. Eilise continued on the ketogenic diet until early 2005, checking in periodically with Johns Hopkins. During her appointments there, the treating physician diagnosed Eilise with "static encephalopathy of unknown etiology" and "intractable atonic seizures, resolved with ketogenic diet." Id. at \*8.

At the time of the hearing in this case, Eilise was seventeen years old, reading at a fifth grade level. Her math skills and handwriting were at a third grade level. Id. at \*9.

#### B. Burden of Proof

Petitioners seek recovery in this case for an "off-Table" injury, that is, an injury caused by a vaccine other than those injuries listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). In off-Table injuries, claimants must show causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A); see also Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). The U.S. Court of Appeals for the Federal Circuit summarized the claimant's evidentiary burden associated with off-Table cases in Althen v. Secretary of Health and Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), holding that he must establish by preponderant evidence:

(1) a medical theory causally connecting the vaccination and the injury;

- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a proximate temporal relationship between vaccination and injury.

These factors are now commonly referred to as the three Althen prongs.

C. Summary of Expert Evidence

To support their claims, Petitioners offered the opinion and testimony of Dr. Yuval Shafrir, a board-certified pediatric neurologist in private practice as well as an assistant professor of pediatrics. Dr. Shafrir viewed Eilise's initial seizure in January 2001 shortly after her vaccination as the onset of "epileptic encephalopathy" which progressed in the next months to increasingly frequent seizures until they were successfully controlled by the ketogenic diet. Tr. 148-49. In Dr. Shafrir's view, the MMR vaccination caused Eilise to have an "immune mediated" response affecting the brain and leading to the seizures, which in turn caused her speech and behavior to regress from the improvement she had achieved just prior to the vaccination. Id. at 159-60. To support his theory, Dr. Shafrir offered several studies of reactions to the MMR vaccine. Expert Report of Dr. Shafrir, Dkt. No. 40. Although these reactions were different from the "autoimmune epileptic encephalopathy" he saw in Eilise's case, Dr. Shafrir offered the studies as proof that the MMR vaccine could cause changes in the brain. It was his opinion that the MMR vaccine's effects on the brain can be viewed as a spectrum, with severe, often fatal conditions on one end, and minor challenges on the other end. Eilise's seizures and developmental damage would fall somewhere on that spectrum. Tr. at 179-80, 217. Dr. Shafrir also testified that in his opinion, the five-to-six day period between Eilise's vaccination and her initial seizure was consistent with his theory, given that this was her second MMR vaccination, and thus an immune response would be provoked more quickly. Id. at 153-54, 161-62.

Respondent's expert was Dr. John MacDonald, who is board-certified in psychiatry and neurology, with a special competence in child neurology and clinical neurophysiology, and an associate professor at a medical school. It was his opinion that there was no evidence linking the MMR vaccination to the seizures, adding that it was common for seizures to have an unknown cause. Id. at 223, 246. He did not see in the medical records evidence of dramatic changes in Eilise's mental status rising to the level of an "acute" brain disorder such as autoimmune encephalopathy, attributing much of her reactions to transitory effects of the seizures themselves together with the anti-seizure medications she was given. Id. at 239-241. He also disputed Petitioners' claim that the seizures caused long term setbacks in Eilise's motor and language development, citing similar test scores both before the seizures began and after the seizures stopped. Id. at 242-43, 246.

#### D. The Special Master's Decision

The Special Master found that Petitioners had failed to meet the burden of proof required to establish the first two prongs set forth in the Althen case. With respect to the first prong requiring proof of a medical theory connecting the vaccination and the injury, the Special Master found Dr. Shafrir's testimony and accompanying literature unpersuasive. He distinguished one study (the "Pampiglione" study) because effects lasted only two weeks, and a second article (the "Gibbs" article) because the effects found were attributed to an intercurrent illness rather than to vaccination. Moriarty, 2014 WL 4387582, at \*11-\*13. He concluded that "petitioners failed to demonstrate that the MMR vaccine can cause an autoimmune epileptic encephalopathy, and failed to meet Althen prong 1." Id. at \*13.

The second Althen prong requires proof of a logical sequence of cause and effect between the vaccine and injury. Again, the Special Master was not convinced. "Dr. Shafrir identified few, if any, solid bases for his conclusion that Eilise suffered from an epileptic encephalopathy that was autoimmune in origin." Id. at \*14. The Special Master found more persuasive Dr. MacDonald's opinion that Eilise showed no clinical signs of an autoimmune encephalopathy, and that patients suffering from seizures caused by that condition are in Dr. MacDonald's experience, "desperately sick." Id. at \*15. Further, the Special Master noted that the doctors treating Eilise during the time of her seizures did not identify an autoimmune reaction. Id. He acknowledged statements in medical records from 2004 and 2005 referring to the 2001 seizures as attributed to the MMR vaccination. However he saw them as only summaries of "remote history," likely provided by Eilise's mother, and not substantiated by any medical records or opinions dating from the period when Eilise was treated for the seizures. Id.

In addressing the third Althen prong, requiring proof of an appropriate time frame to infer causation, the Special Master found that Eilise had suffered a seizure nearly six days after vaccination, and that this was sufficient to prove the requisite timing. Id. at \*16-\*17. However, because Petitioners did not meet their burden of proof on all three Althen prongs, the Special Master ruled that Eilise was not entitled to compensation.

### Discussion

#### A. Standard of Review

This Court has jurisdiction to review decisions of the Special Masters in accordance with 42 U.S.C. § 300aa-12(e)(1)-(2). The Special Master's findings of fact receive deferential review under an "arbitrary and capricious" standard, while the Court reviews legal conclusions under the "not in accordance with law" standard and discretionary rulings for an "abuse of discretion." Munn v. Sec'y of Health & Human

Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). “The arbitrary and capricious standard of review is difficult for [a petitioner] to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact.” Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). “Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.” Moberly, 592 F.3d at 1325.

#### B. Petitioners’ Contentions on Review

In support of their Motion for Review, Petitioners claim that in finding they failed to prove both the first and second prongs required by Althen, the Special Master has required a burden of proof beyond the preponderance of evidence standard specified by the Vaccine Act. With respect to proof of prong one, a medical theory causally connecting the vaccination and injury, Petitioners argue that their expert advanced a “plausible” theory of how the vaccine could have injured Eilise, while the Special Master impermissibly required more: he looked for evidence beyond their expert’s assertion that the MMR vaccine can cause the seizures in Eilise’s case. Pet’rs’ Mot. for Rev. 12-13, Dkt. No. 73. Petitioners assert that “[t]he medical theory that measles vaccination *can* cause encephalopathy is neither new, nor novel,” and that the evidence proffered by Petitioners should be sufficient to prove prong one. Id. at 12. As to proof of prong two, a logical sequence of cause and effect, Petitioners maintain that they cannot be required to prove how vaccines directly affected Eilise, and that proof of a “medically appropriate time” is sufficient. Id. at 19.

Respondent answers that a “preponderance” standard requires proof of a fact more probable than not, a standard of proof higher than the “plausibility” standard urged by Petitioners. Resp’t’s Mem. in Resp. to Pet’rs’ Mot. for Rev. 7-8, Dkt. No. 77 (“Resp’t’s Mem.”). Respondent notes that in proving prong one, “a causation theory must be supported by a ‘sound and reliable’ medical or scientific explanation.” Resp’t’s Mem. 8 (citing Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). Respondent argues that, in Eilise’s case, the Special Master was not persuaded by Petitioners’ expert, and the Special Master’s opinion is entitled to deference upon review by this Court. Id. at 11. Proof of prong two also failed for similar reasons, Respondent claims: because the Special Master determined that Petitioners did not prove that Eilise developed an autoimmune disorder, he properly found that they could not logically connect the vaccine to her seizures. Id. at 15.

#### Conclusion

The Court has considered the parties’ arguments, the evidence of record, and the Special Master’s decision on entitlement. The Court is satisfied that the Special Master

set forth a rational basis for his decision. The Special Master has discretion to assess the reliability of expert testimony when weighing the persuasiveness of the evidence. Moberly, 592 F.3d at 1325-1326. He also appropriately weighed the studies presented by the Petitioners, together with the records of treating physicians, and reasonably concluded that Petitioners failed to prove the first two prongs of the Althen test. Althen mandates that a claimant offer a “*persuasive*” medical theory,” supported by reputable medical or scientific explanation. 418 F.3d at 1278 (emphasis added). The Special Master reasonably determined that Petitioners failed to offer a reliable theory as to how the MMR vaccine can cause autoimmune epileptic encephalopathy, and thus he did not act contrary to law in concluding that Petitioners failed to prove the first prong. With respect to the second prong, the Special Master saw no logical sequence of cause and effect between the MMR vaccine and the seizures Eilise experienced. His finding that Petitioners did not prove that Eilise suffered from an autoimmune disorder is reasonable: there is very little evidence in the record supporting Petitioners’ assertion of an autoimmune reaction. Because the Court is not tasked with reweighing the evidence, and the Special Master’s decision is neither arbitrary nor capricious, the Special Master’s decision is AFFIRMED. Accordingly, Petitioners’ Motion for Review is DENIED.

IT IS SO ORDERED.

s/ Thomas C. Wheeler  
THOMAS C. WHEELER  
Judge